DEC 2 0 2002

CONFIDENTIAL

510(k) Summary

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Date: June 10, 2002

Sponsor: Mitek Worldwide
249 Vanderbilt Avenue
Norwood, MA 02062
Registration #1221934

Contact: Petra C. Smit
Tel: (781) 251-3196
Fax: (781) 278-9578
E-mail: psmit@ethus.jnj.com

Proprietary Name:
Mitek PDS/PGA Staple

Classification Name:
Fastener, Fixation, Biodegradable, Soft Tissue
(21 CFR 888.3030); Class II
Product Code: 87 MAI

Common Name:
Biodegradable Fastener, Soft Tissue Fixation

Predicate Device(s):
K946271 6-0 Coated VICRYL (polyglactin 910) Absorbable Suture
PMA N18331 PDS II Suture
K970119 Mitek "H" Fix Meniscal Fastener

DEVICE DESCRIPTION:

Product Description
The Mitek PDS/PGA Staple is a sterile, implantable device intended for single patient use only. The PDS/PGA Staple consists of an injection molded polydioxanone (PDS) U-shaped strap and two injection molded polyglycolic acid (PGA) cones. The PDS U-shaped strap is insert-molded around the two injection molded PGA cones, resulting in a single, mechanically joined, PDS/PGA Staple construct.

The PDS/PGA Staple is manufactured from two absorbable polymers that are well-known and well-characterized and have been used in a multitude of commercially available medical devices.

Indications for Use
The Mitek PDS/PGA Staple is an absorbable implant used in the fixation of scaffolding (for example periosteal autograft, collagen membranes or synthetic scaffolding) to articular cartilage lesions of the knee.

Safety and Performance.
Biocompatibility data, results of an in vitro strength retention assessment, a simulated use evaluation and results of in vivo animal studies have been provided to support the safety and performance of the PDS/PGA Staple.
The data provided supports that the PDS/PGA Staple is substantially equivalent to currently marketed devices.

CONCLUSION
Based on 1) safety and performance data, and 2) similarities in operating principle, intended use, materials, manufacturing processes and sterilization processes, the PDS/PGA Staple has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2002

Ms. Petra C. Smit
Sr. Project Manager, Regulatory Affairs
Mitek Worldwide
249 Vanderbilt Avenue
Norwood, Massachusetts 02062

Re: K021953
Trade/Device Name: Mitek PDS/PGA Staple
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple Component Metallic Bone Fixation Appliances and accessories
Regulatory Class: Class II
Product Code: JDR
Dated: September 24, 2002
Received: September 25, 2002

Dear Ms. Smit:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

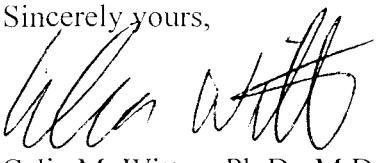
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021953

Device Name: Mitek PDS/PGA Staple

Indications for Use

The Mitek PDS/PGA Staple is an absorbable implant used in the fixation of scaffolding (for example periosteal autograft, collagen membranes or synthetic scaffolding) to articular cartilage lesions of the knee.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes
(Per 21 CFR 801.109)

OR

Over-the -Counter Use No

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K021953